Supporting Statement – Part A

Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CMS-10865)

A. Background

On April 7, 2022, CMS finalized the national coverage determination (NCD) to cover FDA approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of Alzheimer's disease (AD) under coverage with evidence development (CED) in patients who have a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD. For anti-amyloid mAbs that have accelerated approval, the mAb may be covered in a randomized controlled trial conducted under an investigational new drug (IND) application or any NIH sponsored trial.

For antiamyloid mAbs that have traditional FDA approval (as opposed to accelerated approval), the NCD specifies coverage under CED in CMS approved prospective comparative studies, where data may be collected in a registry. In addition to satisfying the study criteria specified in the NCD, CMS approved studies for anti-amyloid mAbs that have received traditional FDA approval must address all of the questions below:

- Does the antiamyloid mAb meaningfully improve health outcomes (i.e., slow the decline of cognition and function) for patients in broad community practice?
- Do benefits, and harms such as brain hemorrhage and edema, associated with use of the antiamyloid mAb, depend on characteristics of patients, treating clinicians, and settings?
- How do the benefits and harms change over time?

In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we must formally reopen and reconsider the policy.

CMS supported development of a registry, the "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry" (mAb Registry), to facilitate coverage under the NCD. Additionally, CMS is working with multiple organizations preparing to open their own registries. Once more registries are available, they will also be listed at https://www.cms.gov/medicare/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad, and clinicians will be able to choose which registry to participate in.

B. Justification

1. Need and Legal Basis

The statutory authority for this policy is section 1862 (a)(1)(E) of the Social Security Act. Section 1862(a)(1)(E) of the Act allows Medicare to cover under CED certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

Consistent with the NCD, Medicare will cover and pay for drugs in the class of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease with traditional FDA approval. To obtain coverage, the provider participates in a data submission effort, commonly referred to as a registry, to further evaluate whether the drug is reasonable and necessary in the Medicare population.

As part of its coverage framework for this class of drugs, CMS is collecting information that will help to evaluate the appropriateness of the treatment for the Medicare population.

2. Information Users

The data collected and analyzed in the CMS-supported mAb Registry and potential CMS-approved registries will be used by CMS to determine if monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD) is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. CMS is collecting information to learn more about which individuals benefit the most from this drug. CMS refers to this as coverage with evidence development or CED. The information being collected via registry will be analyzed to assist clinicians and patients make informed treatment decisions. Furthermore, data from the mAb Registry will assist the pharmaceutical industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of these types of drugs.

3. Use of Information Technology

The data needed for the CMS-supported mAb Registry will be submitted using a web-based data collection tool provided by CMS. It will utilize an easy-to-use format. Whenever possible, drop-down menus will be available.

4. Duplication of Efforts

There is not any data collection of this nature at this time. This information collection does not duplicate any other effort and the information cannot be obtained from any other source. Prior to this policy, there was not data collection of this nature.

5. Small Businesses

The collection of information does not impact small businesses or other small entities.

6. Less Frequent Collection

Clinicians will submit information to this registry when furnishing this drug to people with Medicare who meet the NCD criteria. If the data is not collected, CMS is not able to assess key outcomes of interest and determine the factors that predict clinically meaningful net health benefits and harms.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published XX XX, 2023 (88 FR XXXXX).

Following the national coverage analysis for this NCD, CMS collaborated with Ventera and Yale University to develop the mAb Registry.

9. Payments/Gifts to Respondents

There will be no payments or gift to respondents.

10. Confidentiality

CMS will ensure that all applicable patient confidentiality, privacy, and other Federal laws are complied with, including the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

The burden associated with this requirement is the time and effort necessary for the provider to complete a brief electronic data collection form. The data submission portal is an easy-to-use format. Whenever possible, drop-down menus will be available. Clinicians furnishing this drug will have already gathered this information as part of routine clinical assessment and follow-up care for patients with mild cognitive impairment or mild Alzheimer's disease dementia who are being evaluated for or treated with these medications. The required elements may already be available to the clinician from the patient's medical record.

We estimate it will take trained data entry personnel (most likely nurses employed and assigned by the facility) 5 minutes to submit the required information into the data submission portal at the time the medication is provided. We estimate that approximately 40,000 people with Medicare will receive these medications per year. According to the U.S. Department of Labor (https://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wage for a nurse in 2022 was $42.80. To account for overhead and benefits we have doubled the mean hourly wage which is equal to $85.60. Five minutes to enter the datais 3,320 hours (.083 hours X 40,000 beneficiaries). The annual cost burden is $284,192 (3,320 hours X $85.60).

Number of responses	Hours per response	Annual hour burden	Cost per response	Annual cost burden
40,000	.083	3,320	$6.85	$284,192

We note that this estimate assumes manual data entry for each screening performed and that all estimated eligible Medicare beneficiaries will avail themselves of this covered benefit. The actual estimate will most likely be lower due to options for automatic data uploads from electronic health records and a lesser number of eligible Medicare beneficiaries that choose to avail themselves of these covered services.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

We anticipate that a Grade 14 Step 1 employee will spend 60 hours a year overseeing this endeavor. The locality adjusted wages for a CMS employee at that Grade and Step is $132,368 annually or $63.43 hourly as of 2023. Thus, the annual cost to the Federal government of overseeing the CMS-supported mAb Registry is $3,806.

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

There are currently no publication or tabulation dates.

17. Expiration Date

The expiration date will be included on the data collection forms.

18. Certification Statement

There is no exception to this certification.